



Instructions for Use Reprocessed Mariner Diagnostic Electrophysiology Catheter

Reprocessed Device for Single Use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Reprocessed Mariner steerable/deflectable tip electrode catheter is a flexible, radiopaque catheter constructed of extruded polymer over stainless steel braid. The catheter is designed for intracardiac recording or stimulation. The Mariner catheter handle controls allow precise tip placement within the heart.

INDICATIONS FOR USE

The Reprocessed Mariner catheter is intended for use in diagnostic electrophysiologic procedures. The catheter is designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.

CONTRAINDICATIONS

There are no known contraindications for these catheters.

WARNINGS

- This device should be used only by or under the supervision of physicians well trained in electrophysiology, including the placement and use of intracardiac electrode catheters.
- Do not use catheter for intracardiac ablation or for DC ablation. United states law does not permit the use of this catheter for these types of ablation.
- Use only isolated amplifiers, pacing equipment, and ECG equipment (IEC 60601-1 Type CF equipment, or equivalent) or patient injury or death may occur. Leakage current from any connected device to the patient must not exceed 10 micro Amps (μA) under any circumstance.
- Use the catheter with only Medtronic cables.
- Tactile feedback of reprocessed device may vary during use.

PRECAUTIONS

- Do not attempt to use the reprocessed electrophysiology catheter prior to completely reading and understanding the *directions for use*.
- Do not alter this device.
- Inspect the packaging and catheter for damage or defects prior to use.
- Do not excessively bend or kink the catheter. Excessive bending or kinking may damage internal electrode wires and/or distal tip shaping capabilities.
- Do not allow moisture onto the connectors on the catheter or cables. If the connectors get wet, the system may not function correctly.
- Do not wipe the catheter with organic solvents, such as alcohol, to maintain optimal patient safety and catheter electrode integrity.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).

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ADVERSE REACTIONS

Potential risk and complications are as follows: Perforation of the vasculature is an inherent risk of any catheter placement. Additional potential complications are those attending any intracardiac catheterization procedure including, but not limited to the following: cardiac tamponade, thromboembolic episodes, hematoma, pneumothorax, local or systemic infection, and death.

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the catheter and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the catheter is damaged or if the package is compromised, do not use the catheter. Return the catheter and packaging to Innovative Health. Do not attempt to resterilize.
- Remove the catheter from the package and place it in a sterile work area using aseptic technique.
- Inspect the catheter carefully for electrode integrity and overall condition. Do not use the catheter if the electrodes or tip is loose, misshapen, or otherwise visibly damaged.
- Anticoagulation is to be used at all times during the procedure.
- Create vascular access using sterile techniques. The catheter may be inserted from femoral, brachial, subclavian, or jugular access sites.
- Connect the catheter to the catheter cable.
 - Match connector colors for proper cable to catheter connection.
 - Connect the cable: Align the double arrows on the cable's plastic connector with the external button on the catheter handle connector.
 - Press the connectors together. Do not force the connection.

Note: To disconnect the catheter cable from the catheter, pull back on the grip ring to release the lock before removing the connector.
- Connect the lead pins of the catheter connecting cable to the appropriate electronic recording and/or stimulation equipment. For further information, refer to the catheter connecting cable instructions for use.
- Advance the catheter into the desired area of the heart using fluoroscopic and ECG guidance.
- Handle Control Operation
 - Pull back on the Tip Deflection Control to deflect the tip of the catheter. The tip can be deflected at least 180°. To straighten the tip, push the Tip Deflection Control forward.
 - Rotate the Tip Deflection Control clockwise for greater friction and counter-clockwise for less friction to control the tip position. To maintain tip position, rotate the Tip Deflection Control clockwise to the locked position.
 - Pull back on the Curve Radius Control to increase the deflected curve radius. To decrease the deflected curve radius, push the Curve Radius Control forward.
 - Rotate the Curve Radius Control clockwise for greater friction and counter-clockwise for less friction to adjust the force needed to adjust the force needed to maintain the curve radius.
 - Turn the Lateral Deflection Control clockwise or counter-clockwise to rotate the tip laterally up to 45° in either direction.
 - Before withdrawing the catheter, re-align the marks on the Lateral Deflection Control, push the Tip Deflection Control forward and verify by fluoroscopy that the tip is in a neutral position.

Instructions for Use: Reprocessed Marinr Diagnostic Electrophysiology Catheter

EXPLANATION OF SYMBOLS



Federal Law in the USA restricts this device to sale by or on the order of a physician



Sterilized by Ethylene Oxide Gas



Catalog Number



Serial Number



Lot Number



Use by Date



Do Not Reuse



Do Not Resterilize



Consult Instructions for Use



Do Not Use if Package is Damaged



Keep Product Dry



Keep Away from Sunlight and Radioactive Sources



Non-pyrogenic

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with Ethylene Oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with EO. The packaging may expose you to EO, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Marinr is a registered trademark of Medtronic, Inc.

Please refer to www.innovative-health.com for product warranty.